



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,251	02/24/2004	Stanley W. Olson JR.	02-125 (US02)	2722
41696 7590 07/19/2007 VISTA IP LAW GROUP LLP 12930 Saratoga Avenue Suite D-2 Saratoga, CA 95070			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 07/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/786,251	OLSON ET AL.	
	Examiner	Art Unit	
	Jerry Cumberledge	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-60 and 62-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-60 and 62-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 48-55 are objected to because of the following informalities: In claim 48, line 5, there is a space followed by "serting". This will be considered to be the word "inserting" for examination purposes. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 48-54, 56-58, 60 and 62-67, as best understood by the Examiner, are rejected under 35 U.S.C. 102(e) as being anticipated by Margulies et al. (US Pat. 6,679,890).

Margulies et al. disclose a method for delivering implant material into body tissue using a cannula and plunger assembly comprising a cannula body (Fig. 2b, ref. 20) having a first opening (Fig. 5a, ref. 23) (column 4, lines 50-52) and a second opening (Fig. 2b, ref. 60) proximal to the first opening, the plunger (Fig. 1, ref. 40) slidably disposed within a lumen of the cannula body (column 5, lines 40-42) and having a sealing member (column 9, lines 27-30), the method comprising: inserting the cannula

Art Unit: 3733

body (Fig. 2b, ref. 20) into targeted body tissue (column 5, lines 36-39); perfusing the implant material out of the first opening into the tissue while the sealing member is in a first position relative to the cannula body and distal to the first opening (column 5, lines 45-50); moving the sealing member from the first position to a second position relative to the cannula body and between the first and second openings (column 5, lines 51-53); and perfusing the implant material out of the second opening into the tissue while the sealing member is in the second position (column 5, lines 51-53). The method further comprises severing a distal portion from a proximal portion of the cannula member (column 5, lines 64-67). The method further comprises separating a distal portion from a proximal portion of the cannula body after the implant material is perfused out of the respective first and second openings (column 5, lines 64-67). The implant material is longitudinally perfused out of the cannula body through the first opening (column 5, lines 45-50), and transversely perfused out of the cannula body through the second opening (column 5, lines 51-53). The cannula body further comprises a third opening proximal to the second opening (Fig. 2b, ref. 60), the method further comprising: moving the sealing member from the second position to a third position relative to the cannula body and between the second and third openings (column 5, lines 51-53); and perfusing the implant material out of the third opening into the tissue while the sealing member is in the third position (column 5, lines 51-53). The implant material is bone cement (column 7, lines 18-21). The tissue is bone tissue (column 4, lines 37-39).

Margulies et al. disclose a method for delivering implant material into body tissue using a cannula, the cannula comprising a cannula body (Fig. 2b, ref. 20) having a

proximal end (Fig. 2b, near ref. 26), a distal end (Fig. 22, near ref. 30), and one or more openings (Fig. 2, refs. 23 and 60), the method comprising: inserting the cannula body into body tissue (column 5, lines 36-39); perfusing the implant material out of the one or more openings into the tissue (column 5, lines 45-50)(column 5, lines 51-53); and separating the proximal end from the distal end of the cannula body at a predefined detachment location (column 5, lines 64-67, since the detachment location must be predefined, even if it is only predefined immediately preceding the separating step). The implant material is bone cement (column 7, lines 18-21). The tissue is bone tissue (column 4, lines 37-39). The one or more openings comprises a plurality of openings axially spaced from each other along the cannula body (Fig. 2, refs. 23 and 60), the method further comprising perfusing the implant material out of the plurality of openings into the tissue (column 5, lines 45-53). The cannula further comprises a plunger (Fig. 1, ref. 40) configured to be slidably disposed in a lumen of the cannula body (column 5, lines 40-42), and the one or more openings comprises a first opening (Fig. 2, ref. 23) and a second opening (Fig. 2, refs. 60) proximal to the first opening, the method further comprising: proximally displacing the plunger from a first position distal to the first opening into a second position between the first and second openings (column 5, lines 51-53); and perfusing the implant material out of the second opening into the tissue while the plunger is in the second position (column 5, lines 51-53). Separating the proximal end from the distal end of the cannula body comprises detaching the cannula body by applying a shearing or twisting force (column 5, lines 64-67). Separating the proximal end from the distal end of the cannula body comprises unscrewing the

Art Unit: 3733

proximal end from the distal end (column 4, lines 62-64). The method further comprises implanting the distal end of the cannula body within the tissue (column 5, lines 36-37). The distal end of the cannula body is composed of a biocompatible material (column 6, lines 37-39).

Margulies et al. disclose a method for delivering implant material into body tissue using a cannula and plunger assembly, the cannula comprising a cannula body (Fig. 2b, ref. 20) having a distal end opening (Fig. 2b, near ref. 23) and a wall opening (Fig. 2b any of refs. 60) proximal to the distal end opening (Fig. 2b), the plunger slidably disposed within a lumen of the cannula body (column 5, lines 40-42) and having an attached sealing member (column 9, lines 27-30), the method comprising: inserting the cannula body into targeted body tissue (column 5, lines 36-39); perfusing implant material out of the distal end opening into the tissue while the sealing member is in a first position relative to the cannula body and distal to the distal end opening (column 5, lines 51-53); moving the sealing member from the first position to a second position relative to the cannula body located within the cannula body lumen between the distal end opening and the wall opening (column 5, lines 51-53); and perfusing implant material out of the wall opening into the tissue while the sealing member is in the second position (column 5, lines 51-53). The method further comprises separating a distal portion from a proximal portion of the cannula body after the implant material is perfused out of the respective distal end and wall opening (column 5, lines 64-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-60, 62-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margulies et al. (US Pat. 6,679,890) in view of Reiley et al. (US Pat. 6,248,110 B1).

Margulies et al. disclose the claimed method except for the bone tissue being a vertebral body.

Reiley et al. disclose a method for delivering implant material into tissue using a cannula (column 1, lines 53-65), where the tissue can be either a vertebral body (Fig. 39D) or other bones of the body (column 6, lines 3-8) and the method is used to treat fractures or other conditions of bone systems (column 1, lines 35-38).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have used the method of delivering implant material into tissue using a cannula of Margulies et al. in the vertebra as taught by Reiley et al., in order to treat fractures or other conditions of bone systems (column 1, lines 35-38).

Response to Arguments

Applicant's arguments filed 04/03/2007 have been fully considered but they are not persuasive.

With regard to Applicant's argument that Margulies et al. do not disclose an attached sealing member, the Examiner respectfully disagrees. As can be seen in from the passage in column 9, lines 27-30, Margulies et al. do disclose the use of a sealing member.

With regard to Applicant's argument that Margulies et al. do not disclose separating the distal end of the cannula body at a predetermined detachment location, the Examiner respectfully disagrees. The detachment location must be predefined, even if it is only predefined immediately preceding the separating step, in order for the surgeon to remove the appropriate amount of the cannula body (i.e. the amount that is exposed). In other words, the exposed portion of the cannula will be visually predetermined by the surgeon prior to its subsequent removal.

With regard to Applicant's argument that there is no mention of a shearing or twisting force in Margulies et al., the Examiner respectfully disagrees. The act of detaching the distal end portion will require that at least a shearing force be applied at some place along the portion of the device that is being cut.

With regard to Applicant's argument that there is no mention of separating the proximal end from the distal end of the cannula body by unscrewing the proximal end from the distal end, the Examiner respectfully disagrees. The definition of "unscrewing" according to the Cambridge Dictionary of American English, is "to remove (the lid or top) from something by twisting it, or to remove (screws) from something". Both of these definitions apply in this case. The top of the implant is being removed, and there will be some twisting involved with the removal, even if only small twists due to the

Art Unit: 3733

unsteadiness of the surgeons hands. Furthermore, the portion of the device with the threads can be considered to be a screw, and since at least a portion will be removed from the this threaded portion, a "screw" will be removed from "something", in this case the "something" being the rest of the device.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER